REMARKS

Claims 11-22 are pending and rejected in the application.

Rejection of Claim 11 as Anticipated by Schramm et al. '101

The Examiner rejects Claim 11 as anticipated by US 5,476,101 to Schramm et al. This rejection is improper for at least the following reasons.

Anticipation requires the reference in question teach every aspect of the claimed invention (MPEP706.02). In particular, a claim is anticipated only if each and every element set fourth in the claim is found in a single prior art reference (See MPEP 2131). It is respectfully urged that Schramm et al. '101 does not each and every element of Claim 11.

For example, Claim 11 recites, in part:

> "an inner member having a distal portion which is biased to expand radially at its distal end....., and said inner member distal portion expands radially to capture a tissue sample as said inner member moves distally;....."

It is respectfully urged that Schramm et al. '101 does not teach an inner member having a distal portion biased to expand radially at its distal end. Nor does Schramm et al. 101 teach or suggest an inner member distal portion that expands radially as the inner member moves distally.

Rather, Schramm et al. '101 teaches a first needle 86 and a second needle 96. Schramm et al. '101 further states that first needle 86 is a substantially solid shaft 87 with a tissue holding region 90 cut-out from shaft 87. (See Column 11, lines 50-62).
It is respectfully urged that the substantially solid shaft 87 of Schramm et al. '101 does not teach or suggest radial expansion as recited in claim 11.

Further, Claim 11 recites in part:

> "wherein said outer hollow cannula is slideable relative to said inner member such that, when said outer hollow cannula is extended distally, said distal end portion of said inner member is forced by said outer hollow cannula to close about and sever the tissue sample....."

It is respectfully urged that Schramm et al. '101 does not teach or suggest an inner member having a distal end portion that is forced by an outer hollow cannula to close about a tissue sample.

Accordingly, the rejection of Claim 11 as anticipated by Schramm '101 is improper for at least the reasons provided above, and should be withdrawn.

REJECTION OF CLAIMS 12, 14, 15, 17-19, 21, AND 22 AS OBVIOUS OVER SCHRAMM ET AL. '101 IN VIEW OF SPRINGER

It is respectfully urged that this rejection is improper for at least the following reasons.

First, it is respectfully urged that Schramm et al. '101 has been misapplied by the Examiner for all the reasons set forth above with respect to the rejection of Claim 11.

Second, it is respectfully urged that the Examiner has not met the burden of providing a prima facie case of obviousness. A prima facie case of obviousness requires that three basic criteria be met: 1. There must be some suggestion or motivation in the prior art to modify a reference or combine reference teachings; 2. There must be a reasonable expection of success; and 3. The references when combined must teach or suggest all the claim limitations. (See MPEP 2143).

No Suggestion or Motivation for Combination

It is respectfully urged that the Examiner has not shown where or how the prior art suggests the combination of the two references to obtain the claimed invention. The Examiner merely concludes (without further support or reasoning) that because Springer teaches a biopsy instrument having an inner member with a distal end in the shape of an alligator clip, it would

be obvious to use such a clip at the distal end of the device in Schramm et al. '101. The mere fact that the reference could be combined is not sufficient (See MPEP 2143), and it is respectfully urged that the Examiner's conclusory statement, without more, is not sufficient to establish a prima facie case of obviousness.

Further, it is respectfully urged that the Examiner has ignored significant differences between the Springer device and the Schramm et al. '101 device that would teach away from such a combination. For instance, Schramm et al. '101 discloses a device with first and second needles. Both needles of the biopsy system in Schramm et al. '101 are inserted into a tissue to be sampled (see column 11, lines 58-62). In contrast, the Springer device does not appear to be meant for insertion into tissue. Instead, the Springer device is disclosed as being inserted into the rectum to obtain tissue or excrement specimens during a proctological exam or operation (column 1, lines 20-25), i.e. in body channels (column 1, lines 39-40). It is respectfully urged that one would not be motivated to combine a portion of a medical instrument that is inserted into tissue with a portion of a medical device that is meant to be inserted into a body channel.

Further, the rejection is improper because the proposed modification would render Schramm et al. device unsatisfactory for its purpose. There is no suggestion or motivation for the combination of references if the proposed modification would render the prior art invention unsatisfactory for its intended purpose. See MPEP 2143. It is respectfully urged that if one added jaws of Springer to the distal end of the inner needle of Schramm et al. '101', as suggested by the Examiner, then the Schramm et al. device would no longer be satisfactory for its intended purpose because it would not have the point necessary to enter the tissue to be sampled (see Schramm et al. '101' at column 12, lines 2-5 and lines 12-18 explaining the point of the inner needle is exposed at all substantial times of operation).

Accordingly, it is respectfully urged one would not be motivated to combine the references as suggested by the Examiner, especially where the Examiner's proposed combination would render the Schramm et al. device unsatisfactory for it's intended purpose.

No Reasonable Expectation of Success

The rejection is also improper because there is no reasonable expectation that the Examiner's proposed combination would work to obtain a biopsy specimen within a tissue sample. As explained above, if the jaws of Springer are added to the end of the needle of Schramm et al. '101', as suggested by the Examiner, it appears that it would difficult, if not impossible, to enter the tissue sample with the resulting device.

Combination Does Teach or Suggest All Claim Limitations

The rejection is also improper because the combination suggested by the Examiner does not teach or suggest each and every claim limitation. For instance, Claim 12 depends from Claim 11. As explained above with respect to the 102 rejection, the Schramm et al. '101' reference does not teach or suggest each and every element of Claim 11. Nor does the Springer reference fill the gaps left by Schramm et al. '101. Accordingly, the cited combination does not teach or suggest all the claim limitations of Claim 12, which depends on Claim 11.

With respect to Claim 17, the Examiner is respectfully asked to explain how the combination of the two references would teach or suggest all the steps of piercing tissue with an instrument comprising an outer hollow cannula and an inner member at least partially disposed in the cannula, positioning the cannula in the tissue, actuating a first mechanism to move the distal end of the inner member distally relative to the cannula so that the distal end portion expands radially and engages tissue, actuating a second mechanism to move the outer hollow cannula distally to radially retract the distal end portion, and withdrawing the instrument with the tissue sample.

It is respectfully urged that even if the Examiner combined the references, the combined references do not teach and suggest each of the steps recited.

REJECTION OF CLAIMS 13, 14, 16, AND 20 AS OBVIOUS OVER SCHRAMM ET AL. '101 IN VIEW OF REZNICK ET AL.

Claims 13, 14, 16, and 20 are rejected as obvious over Schramm et al. '101 in view of Reznick et al. It is respectfully urged that this rejection is improper for at least the following reasons.

First, it is respectfully urged that Schramm et al. '101 has been misapplied by the Examiner for all the reasons set forth above with respect to the rejection of Claim 11.

Second, it is respectfully urged that the Examiner has not met the burden of providing a prima facie case of obviousness.

No Suggestion or Motivation for Combination

It is respectfully urged that the Examiner has not shown where or how the prior art suggests the combination of the two references to obtain the claimed invention. The Examiner merely concludes (without further support or reasoning) that because Reznick et al. teach a biopsy instrument having an inner member with a distal end in the shape of a plurality of hook extractors, it would be obvious to use such hooked extractors at the distal end of the device in Schramm et al. '101. The mere fact that the reference could be combined is not sufficient, and it is respectfully urged that the Examiner's conclusory statement, without more, is not sufficient to establish a prima facie case of obviousness.

Further, it is respectfully urged that the Examiner has ignored significant differences between the Reznick et al. device and the Schramm et al. '101 device. As explained above with respect to the Springer reference, Schramm et al. '101 discloses a device with first and second needles. Both needles of the biopsy system in Schramm et al. '101 are inserted into a tissue to be sampled (see column 11, lines 58-62).

In contrast, the Reznick et al. device does not appear to be meant for insertion into tissue. Instead, the Reznick device is meant to be inserted into a second incision to remove bone fragements (See column 1, lines 18-26). It is respectfully urged that one would not be motivated to combine a portion of a medical instrument that is inserted into tissue with a portion of a medical device that is meant to be inserted into a pre-existing incision.

Further, the rejection is improper because the proposed modification would render Schramm et al. device unsatisfactory for its purpose. It is respectfully urged that if one added the hooked extractors of Reznick et al. to the distal end of the inner needle of Schramm et al. '101', as suggested by the Examiner, then the Schramm et al. device would no longer be satisfactory for its intended purpose because it would not have the point necessary to enter the tissue to be sampled (see Schramm et al. '101' at column 12, lines 2-5 and lines 12-18 explaining the point of the inner needle is exposed at all substantial times of operation).

Accordingly, it is respectfully urged one would not be motivated to combine the references as suggested by the Examiner, especially where the Examiner's proposed combination would render the Schramm et al. device unsatisfactory for it's intended purpose.

No Reasonable Expectation of Success

The rejection is also improper because there is no reasonable expectation that the Examiner's proposed combination would work to obtain a biopsy specimen within a tissue sample. As explained above, if the hooked extractors are added to the end of the needle of Schramm et al. '101', as suggested by the Examiner, it appears that it would difficult, if not impossible, to enter the tissue sample with the resulting device.

Combination Does Teach or Suggest All Claim Limitations

The rejection is also improper because the combination suggested by the Examiner does not teach or suggest each and every claim limitation. For instance, Claim 12 depends from Claim 11. As explained above with respect to the 102 rejection, the Schramm et al. '101' reference does not teach or suggest each and every element of Claim 11. Nor does the Reznick et al. reference fill the gaps left by Schramm et al. '101. Accordingly, the cited combination does not teach or suggest all the claim limitations of Claim 12, which depends on Claim 11.

With respect to Claim 20, which depends from Claim 17, it is respectfully urged that the Examiner has not shown how the combined references would teach all the limitations of Claim 17, as noted above.

Conclusion:

The Examiner is requested to reconsider the pending claims in light of the Remarks above, and to allow the claims in the next office action.

Respectfully submitted,

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